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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,196	02/15/2002	Matti Huiku	50003-00002	9506

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MARSH, FISCHMANN & BREYFOGLE LLP
3151 SOUTH VAUGHN WAY
SUITE 411
AURORA, CO 80014

EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,196

Applicant(s)

HUIKU, MATTI

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-23 is/are allowed.
- 6) ☒ Claim(s) 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 25-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 6,104,938 to Huiku et al. Huiku et al. discloses the use of emitter means for emitting radiation at two different wavelengths (column 13, lines 29-48 of Huiku et al.), detector means (column 14, lines 49-65 to Huiku et al.), and a memory in the sensor probe (column 8, lines 20-31 of Huiku et al.). The Examiner would like to note that the teaching of the means for emitting radiation, means for receiving said radiation, and storage means for storing reference data are the only components that are required apparatus of claim 25. The specifics of the data are not read into the claim since the limitations do not limit the structure of the claimed inventions. In other words, the limitations “for storing reference data indicating nominal characteristics describing calibration conditions when radiation is emitted between said emitter and said detector free of living tissue using a nominal calibration” is describing the function for the means-plus-function limitation. The corresponding structure for this limitation is a memory and Huiku et al. teaches a memory. The limitation “said data allowing an apparatus connected to the sensor to determine tissue-induced changes in

the nominal characteristics when radiation is emitted through living tissue" was not given patentable weight since this limitation is narrowing the term "data," which is only used for describing the function in the means-plus-function limitation of "storage means for storing reference data." In regard to claim 26, LEDs are used. (Fig. 3 of Huiku et al.). In regard to claims 28-29, fiber optics can be used. (column 9, lines 7-20 of Huiku et al.). In regard to claims 30-31, the added limitations related to the reference data were not given patentable weight since these limitations are narrowing the term "data," which is only used for describing the function in the means-plus-function limitation of "storage means for storing reference data."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,104,938 to Huiku et al. (cited by Applicant) as applied to claim 25, and further in view of U.S. Patent 5,348,003 to Caro. Huiku et al. does not teach the use of lasers. The combination teaches the use of LEDs. (column 13, lines 29-47 of Huiku et al.). It is well known in the art that lasers are suitable substitutes for LEDs and they are functionally equivalent. (column 9, lines 42-50 of Caro). Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to substitute lasers for the LED to since they are functionally equivalent and Caro teaches that they are suitable substitutes.

5. Claims 25-26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,968,137 to Yount in view of U.S. Patent 6,104,938 to Huiku et al. Yount discloses a means for emitting two different wavelengths and means for receiving the light (column 1, lines 58-66 of Yount). Yount does not teach placing a memory in the sensor probe. Huiku et al. teaches the placing the calibration data in the sensor is advantageous since calibrations are sensor specific. (column 8, lines 20-31 and column 20, lines 30-33 of Huiku et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the calibration data in the sensor as disclosed by Huiku et al. since Huiku et al. teaches the placing the calibration data in the sensor is advantageous because calibrations are sensor specific. In regard to claim 25, the reference data indicates nominal characteristics describing calibration conditions when radiation is emitted between the emitter and detector free of living tissue since the calibration uses filters. (column 7, line 45 to column 8, line 68 of Yount). In regard to claim 26, Yount teaches the use of light sources (column 1, lines 58-66 of Yount). Huiku teaches that LEDs are suitable light sources. (Fig. 3 of Huiku et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use LEDs as disclosed by Huiku et al. since Yount teaches that light sources can be used and Huiku et al. teaches such light sources. In regard to claims 28-29, the combination does not teach the use

of fiber optics. Huiku et al. teaches that using fiber optics can keep warming elements away from the skin. (column 9, lines 7-20 of Huiku et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the optical fibers of Huiku et al. since such fiber optics keep warming elements away from the skin.

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,968,137 to Yount in view of U.S. Patent 6,104,938 to Huiku et al. as applied to claim 25, and further in view of U.S. Patent 5,348,003 to Caro. Yount teaches the use of light sources (column 1, lines 58-66 of Yount). Huiku teaches that LEDs are suitable light sources. (Fig. 3 of Huiku et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use LEDs as disclosed by Huiku et al. since Yount teaches that light sources can be used and Huiku et al. teaches such light sources. The combination does not teach the use of lasers. It is well known in the art that lasers are suitable substitutes for LEDs and they are functionally equivalent. (column 9, lines 42-50 of Caro). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute lasers for the LED to since they are functionally equivalent and Caro teaches that they are suitable substitutes.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,104,938 to Huiku et al. (cited by Applicant) in view of U.S. Patent 5,725,480 to

Oosta et al. Huiku et al. discloses a method and apparatus for determining the relative concentration of oxyhemoglobin, deoxyhemoglobin, and dyshemoglobin by using light absorption. (Abstract of Huiku et al.). Huiku et al. discloses the use of emitter means for emitting radiation at two different wavelengths (column 13, lines 29-48 of Huiku et al.) and detector means (column 14, lines 49-65 to Huiku et al.). The method and apparatus of Huiku et al. discloses a method of calibration by carrying out initial characterization measurements, establishing nominal characteristics, and storing the reference data. (column 20, lines 7-29 of Huiku et al.). Huiku et al. does not teach determining tissue-induced changes and compensating for subjects specific variation. Oosta et al. teaches a process for determining the contribution of one or more skin parameters to the absorption and transmittance data and correcting the subsequent non-invasive measurement of a biological compound for the contribution of the skin parameters. (Abstract of Oosta et al.). Such correction procedures would result in more accurate measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the correction procedures of Oosta et al. in the method of Huiku et al. since more accurate measurements can be achieved. Oosta et al. teaches that the skin parameters can be programmed into an algorithm for measuring a biological compound. (column 6, lines 51-54 of Oosta et al.). In regard to claims 24, the combination teaches an apparatus which includes a light source for emitting at least two wavelengths (emitter means); a receiver receiving light from the tissue and providing output signals responsive to the received light (detector means); means coupled to said receiver for processing the output signals from the receiver (first

processing means); a reader means coupled to said data storage device for obtaining extinction coefficient data (second processing means); a data storage device storing extinction coefficient data (memory means); and calculating means coupled to said processing means and said reader means for determining the amount of light absorbing substance in the blood. (claim 47 of Huiku et al.). The combination further teaches a first compensation and a second compensation algorithm (column 7, lines 18-42 of Oosta et al.) and it is well known in the art to use a microprocessor to carry out algorithms. (reference numeral 11 of Fig. 6 of Huiku et al.). The Examiner would like to note that the specifics of the reference data are not read into the claim since the limitations do not limit the structure of the claimed inventions. In other words, the limitations "for storing reference data indicating nominal characteristics under which said predetermined calibration has been applied to output signals free of filtering by living tissue" is describing the function for the means-plus-function limitation. The corresponding structure for this limitation is a memory and Huiku et al. teaches a memory.

Allowable Subject Matter

8. Claims 1- 23 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 1, the prior art does not teach or suggest determining tissue-induced changed in the nominal characteristics based on the in-vivo measurements and

the reference data wherein the reference data includes data from characterization measurements made when there was no tissue during transmission.

Response to Arguments

10. Applicant's arguments with respect to claims 25-31 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 7/25/2003 have been fully considered but they are not persuasive. In regard to claim 24, the Applicants attack the Huiku/Oosta combination by attacking the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner contends that the Huiku/Oosta combination does read on claim 24 because the limitation that the Applicant relies, i.e., there is no teaching of an apparatus wherein differences between off-line measurements and on-line measurements are utilized to alter a nominal calibration according to subject-specific variations, is not claimed in claim 24. The Applicant relies on the amended language "memory means for storing reference data indicating nominating characteristics under which said predetermined calibration has been applied to output signals free of filtering by living tissue." The Examiner would like to note that the specifics of the reference data are not read into the claim since the limitations do not limit the structure of the claimed inventions. In other words, the

limitations "for storing reference data indicating nominal characteristics under which said predetermined calibration has been applied to output signals free of filtering by living tissue" is describing the function for the means-plus-function limitation. The corresponding structure for this limitation is a memory and Huiku et al. teaches a memory.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

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0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew Kremer
Assistant Examiner
Art Unit 3736



MAX HINDENBURG
SUPERVISOR
ELECTRONIC BUSINESS CENTER 3700